

## Department of Health and Human Services

## § 170.503

as certain ongoing responsibilities for an ONC-AA.

[76 FR 1325, Dec. 7, 2011, as amended at 77 FR 54291, Sept. 4, 2012]

EFFECTIVE DATE NOTE: At 79 FR 54479, Sept. 11, 2014, §170.501 was amended by designating the existing text as paragraph (a) and by adding paragraph (b), effective Oct. 14, 2014. For the convenience of the user, the added text is set forth as follows:

### § 170.501 Applicability.

\* \* \* \* \*

(b) References to the term Complete EHR and Complete EHR certification throughout this subpart do not apply to certification in accordance with any edition of certification criteria that is adopted by the Secretary under subpart C after the 2014 Edition EHR certification criteria.

### § 170.502 Definitions.

For the purposes of this subpart:

*Applicant* means a single organization or a consortium of organizations that seeks to become an ONC-ACB by submitting an application for ONC-ACB status to the National Coordinator.

*Deployment site* means the physical location where a Complete EHR, EHR Module(s) or other type of HIT resides or is being or has been implemented.

*Development site* means the physical location where a Complete EHR, EHR Module(s) or other type of HIT was developed.

*Gap certification* means the certification of a previously certified Complete EHR or EHR Module(s) to:

(1) All applicable new and/or revised certification criteria adopted by the Secretary at subpart C of this part based on the test results of a NVLAP-accredited testing laboratory; and

(2) All other applicable certification criteria adopted by the Secretary at subpart C of this part based on the test results used to previously certify the Complete EHR or EHR Module(s).

*ONC-Approved Accreditor or ONC-AA* means an accreditation organization that the National Coordinator has approved to accredit certification bodies under the ONC HIT Certification Program.

*ONC-Authorized Certification Body or ONC-ACB* means an organization or a consortium of organizations that has applied to and been authorized by the

National Coordinator pursuant to this subpart to perform the certification of Complete EHRs, EHR Module(s), and/or other types of HIT under the ONC HIT Certification Program.

*Providing or provide an updated certification* means the action taken by an ONC-ACB to ensure that the developer of a previously certified EHR Module(s) shall update the information required by §170.523(k)(1)(i), after the ONC-ACB has verified that the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and that no new certification criteria are applicable to the EHR Module(s).

*Remote certification* means the use of methods, including the use of web-based tools or secured electronic transmissions, that do not require an ONC-ACB to be physically present at the development or deployment site to conduct certification.

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### § 170.503 Requests for ONC-AA status and ONC-AA ongoing responsibilities.

(a) The National Coordinator may approve only one ONC-AA at a time.

(b) *Submission*. The National Coordinator will publish a notice in the FEDERAL REGISTER to announce the 30-day period during which requests for ONC-AA status may be submitted. In order to be considered for ONC-AA status, an accreditation organization must submit a timely request in writing to the National Coordinator along with the following information to demonstrate its ability to serve as an ONC-AA:

(1) A detailed description of the accreditation organization's conformance to ISO/IEC17011:2004 (incorporated by reference in §170.599) and experience evaluating the conformance of certification bodies to ISO/IEC Guide 65:1996 (incorporated by reference in §170.599);

(2) A detailed description of the accreditation organization's accreditation, requirements as well as how those requirements would complement the Principles of Proper Conduct for ONC-ACBs and ensure the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods;